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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/846,933      04/30/97      CLELAND      J      P0825BC3

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EXAMINER

HINES, J

ART UNIT

PAPER NUMBER

1645

*25*

DATE MAILED:

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/846,933

Applicant(s)

Cleland et al.

Examiner

Ja-Na Hines

Group Art Unit

1645



☒ Responsive to communication(s) filed on Aug 6, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1, 4-9, and 23-28 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1, 4-9, and 23-28 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on June 14, 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/846,933 is acceptable and a CPA has been established. An action on the CPA follows.

### ***Amendment Entry***

2. The amendment filed August 6, 2000 has been entered. Amendments to the specification have been entered. Claim 1 has been amended. New claim 28 have also been added. Claims 1, 4-9, 23-27 are pending.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 4-9, 23-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants states that "individual microspheres" having a triphasic profiles is inherent in the description of the triphasic profile of microsphere and is

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referred to at page 45, lines 43-47, however this inherence is not found within the specification. Applicant asserts that the specification provides support for the term "third antigen burst phase" at pages 23, lines 20-22, Table 6, Figure 8, and at pages 46-47, line 16-14.

*Response to Arguments*

4. Applicant's arguments filed August 6, 2000 have been fully considered but they are not persuasive.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 4-9 and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders et al., in view of Eldridge et al., and further in view of Jeffery et al., is maintained.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, the combined teachings of the prior art suggest to a person of skill in the art that compositions containing various volumes of antigen can be encapsulated into microspheres for controlled release of the antigen. Therefore, it

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would have been obvious at the time of applicants invention to use various volumes of antigen incorporated into PLGA, as taught by Jeffery et al., to produce vaccine preparations with different concentrations of antigens that can be released over a variety of time periods as taught by Sanders et al., in view of Elrdridge et al.

Applicant argues that Sanders does not teach or suggest triphasic release profiles as stated in the newly amended claim. However, Sanders et al., specifically teaches microspheres that have triphasic release profiles and models which provide for the reliable indication of the duration of compound release. Sander et al., also teaches several factors such as parameters of the copolymer, the molecular weight and polymer composition, and intrinsic viscosity that affect the release profile. Further, Elrdridge et al. Teaches using a combination of variables to achieve discrete releases of antigens. Therefore, Sanders et al., teaches the inventive concept of a triphasic release microsphere where the antigen is released over a period of time that is encompassed by the applicant's claims.

6. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders et al., in view of Elrdridge et al., and further in view of Jeffery et al., (as applied to claims 1, 4, 9 and 23-28) and further in view of Wang et al., is maintained for reasons of record. Applicants argue that Wang et al., does not teach or suggest triphasic release profile meeting the claim limitations of the specification. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based

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on combinations of references. Wang et al., teaches that it is known in the art of vaccination to combine adjuvants with antigens and to combine the two elements for release from microsphere. Therefore it would have been obvious at the time of applicants invention to encapsulate an adjuvant in the antigen-encapsulated microspheres taught in the prior art because the adjuvant would be expected to enhance the immune response of a vaccine composition and may add the advantage of a higher initial release of the antigen and more efficient protein loading as taught by Wang et al.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders et al., in view of Eldridge et al., and further in view of Jeffery et al., (as applied to claims 1, 4, 9 and 23-28) and further in view of Newman et al., is maintained for reasons of record. In response to applicant's argument that there is no suggestion to combine the references because Newman does not teach microspheres and the other references do not teach the adjuvant QS21, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, no more than routine skill was required to use the known adjuvant QS21, in vaccine composition as taught by the cited references since QS21 can be used as a safe non-toxic adjuvant which augments both antibody responses and cell-mediated immunity.

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8. Claims 1, 4, 9 and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Floy et al. Applicant argues that Floy et al., presents no new data and does not teach or suggest the elements of triphasic releases. Applicants mere arguments do not equate to evidence to the contrary or evidence of unexpected results. Floy et al., teaches drug release profiles from microspheres which typically exhibit a triphasic release pattern. Floy et al., also teaches multiple factors which affect the release profiles and that parameters can be varied for optimization of the delivery system. As previously stated, the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Accordingly, it would have been obvious at the time if applicants invention to make and/or use encapsulated antigens within microspheres of various diameter, compositions, and viscosity in order to deliver the antigen for release in various amounts and at various duration, absent evidence to the contrary or unexpected results.

9. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Floy et al., Sanders et al., (as applied to claims 1, 4, 9 and 23-28) in view of Immunization Practices Advisory Committee. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, it would have been

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obvious to combine the two elements in a microsphere, absent evidence to the contrary or unexpected results.

10. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Floy et al., Sanders et al., (as applied to claims 1, 4, 9 and 23-28) in view of Immunization Practices Advisory Committee and in further view of Newman et al. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, it would have been obvious to one of ordinary skill in the art to include QS21 as an adjuvant in the vaccine composition as taught by the above reference since QS21 can be used as a safe adjuvant known for its ability to establish immunological memory.

11. This is a continuation of applicant's earlier Application No. 08/846,933. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MEP. § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines 

October 18, 2000

  
JENNIFER GRASER  
PATENT EXAMINER